UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,936	02/27/2002	Jeffrey G. Moore	108236.130	8344

23483 7590 05/18/2004

HALE AND DORR, LLP
60 STATE STREET
BOSTON, MA 02109

EXAMINER	
KOSAR, ANDREW D	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,936	MOORE, JEFFREY G.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to a method for protecting a progenitor cell against a cytotoxic agent, classified in class 435, subclass 325+, for example.

II. Claims 12-20, drawn to a method for protecting a progenitor cell in a patient against a progenitor cell-depleting activity of a therapeutic treatment in a patient, classified in class 435, subclass 366+, for example.

III. Claims 21-26, drawn to a method for isolating a cell for repairing a tissue, classified in class 435, subclass 325+, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case invention I is directed towards a method of protecting a progenitor cell against a cytotoxic agent, invention II is directed towards a method of protecting a progenitor cell against cell-depleting activity and invention III is directed towards a method for isolating a cell for repairing a tissue.

One would not have to practice the art recited in Invention I or II to obtain the results from the practice of Invention III. Isolation of a cell for repair is not dependent on

protection of a progenitor cell against cytotoxicity or protection from progenitor cell-depleting activity. Similarly, Invention I and/or Invention II can be practiced independent of each other, as protection from a cytotoxic agent is not necessary to protect against cell-depletion.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for Group I is not required for Group II or III, restriction for examination purposes as indicated is proper.

If Applicant elects Invention I (Claims 1-11):

Claims 1-11 are generic to a plurality of disclosed patentably distinct species comprising a FRIL family member molecule. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 1-4 and 6-11 are generic to a plurality of disclosed patentably distinct species comprising a progenitor cell. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 5 is generic to a plurality of disclosed patentably distinct species comprising:

A) a messenchymal progenitor cell

B) a hematopoietic stem cell

C) a hair follicle progenitor cell

D) a skin progenitor cell

E) a liver progenitor cell

F) a gastrointestinal progenitor cell

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 1-9 and 11 are generic to a plurality of disclosed patentably distinct species comprising a cytotoxic agent. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 10 is generic to a plurality of disclosed patentably distinct species comprising:

A) a chemotherapeutic

B) a radiotherapeutic

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

If Applicant elects Invention II (Claims 12-20):

Claims 12-20 are generic to a plurality of disclosed patentably distinct species comprising a progenitor cell. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 12-20 are generic to a plurality of disclosed patentably distinct species comprising a patient. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 12-20 are generic to a plurality of disclosed patentably distinct species comprising a progenitor cell-depleting activity. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 12-20 are generic to a plurality of disclosed patentably distinct species comprising a therapeutic treatment. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 12-20 are generic to a plurality of disclosed patentably distinct species comprising a therapeutically effective amount of a FRIL family member molecule. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 12-20 are generic to a plurality of disclosed patentably distinct species comprising a FRIL family member molecule. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 13 is generic to a plurality of disclosed patentably distinct species comprising a human. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 14 is generic to a plurality of disclosed patentably distinct species comprising cancer. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 15 and 16 are generic to a plurality of disclosed patentably distinct species comprising:

A) a radiotherapeutic

B) a chemotherapeutic

C) a combination of a radiotherapeutic and a chemotherapeutic

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 16 is generic to a plurality of disclosed patentably distinct species comprising:

A) cytarabine

B) doxorubicin

C) cisplatin

D) daunorubicin

E) paclitaxel

F) cyclophosphamide

G) 5-fluorouracil

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

If Applicant elects Invention III (Claims 21-26):

Claims 21-26 are generic to a plurality of disclosed patentably distinct species comprising a cell. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 21-26 are generic to a plurality of disclosed patentably distinct species comprising a tissue. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 21-26 are generic to a plurality of disclosed patentably distinct species comprising a population of cells. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 21-26 are generic to a plurality of disclosed patentably distinct species comprising a FRIL family member molecule. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 22 and 24 is generic to a plurality of disclosed patentably distinct species comprising a progenitor cell. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 23 is generic to a plurality of disclosed patentably distinct species comprising a human. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 25 is generic to a plurality of disclosed patentably distinct species comprising:

A) a messenchymal progenitor cell

B) a hematopoietic stem cell

C) a hair follicle progenitor cell

D) a skin progenitor cell

E) a liver progenitor cell

F) a gastrointestinal progenitor cell

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 25 is generic to a plurality of disclosed patentably distinct species comprising:

A) whole blood

B) umbilical cord blood

C) fetal liver cells

D) bone marrow cells

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571)272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1654

Andrew D. Kosar
11 May 2004

PATRICIA LEITH
PRIMARY EXAMINER